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February 10, 2000

By Hand

Ms. Jennie C. Butler
Dockets Management Branch (HFA-305)
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20852

Re: Citizen Petition

Dear Ms. Butler:

Enclosed for filing are the original and three copies of a Citizen Petition submitted on behalf of the National Cheese Institute, Grocery Manufacturers of America, Inc., and National Food Processors Association. Kindly date-stamp the fourth copy and return it to me via the awaiting messenger.

Thank you for your assistance.

Sincerely yours,

Coleen E. Klasmeier

CEK/vrj

Enclosures

International Dairy Foods Association
Milk Industry Foundation
National Cheese Institute
International Ice Cream Association

February 10, 2000

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Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20852

CITIZEN PETITION

The undersigned National Cheese Institute (NCI), joined by the Grocery Manufacturers of America, Inc. (GMA) and the National Food Processors Association (NFPA), submits this petition under sections 401 and 701(e) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. §§ 341 and 371(e), to request the Commissioner of the Food and Drug Administration (FDA) to amend section 133.3 of FDA regulations to recognize formally that filtered milk is a form of milk encompassed by the terms "milk" and "nonfat milk" under the standards of identity for cheese and cheese products (21 C.F.R. Part 133). This petition conforms with the requirements for citizen petitions set forth in FDA regulations. See 21 C.F.R. § 10.30.

Founded in 1927, NCI is affiliated with the International Dairy Foods Association and represents manufacturers, marketers, processors, and distributors of a wide variety of cheese and cheese products. Its 95 member companies market approximately 80 percent of the natural and processed cheese and cheese products sold in the United States and would be affected by the amendments proposed in this petition.

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GMA is the world's largest association of food, beverage, and consumer product companies. With U.S. sales of more than $450 billion, GMA members employ more than 2.5 million workers in all 50 States. The organziation applies legal, scientific, and political expertise from its member companies to vital food, nutrition, and public policy issues affecting the industry. Led by a board of 42 Chief Executive Officers, GMA speaks for food and consumer product manufacturers at the state, federal, and international levels on legislative and regulatory issues. The association also leads efforts to increase productivity, efficiency, and growth in the food, beverage, and consumer products industry. GMA counts among its members a number of companies whose product lines include dairy products which would be affected by the amendments proposed in this petition.

NFPA is the voice of the $460 billion food processing industry on scientific and public policy issues involving food safety, nutrition, technical, and regulatory matters and consumer affairs. NFPA's three scientific centers, its scientists and professional staff represent food industry interests on government and regulatory affairs and provide research, technical services, education, communications, and crisis management support for the Association's U.S. and international members, who produce processed and packaged foods, drinks, and juices, including a variety of dairy products. NFPA represents more than 40 companies whose product lines include dairy foods and thus would be affected by the amendments proposed in this petition.

Over the past 20 years, cheese manufacturers have widely adopted the use of milk filtration technology and the resulting filtered milk products in the manufacture of cheese under the alternate make procedures provisions in FDA's standards of identity for cheese. Milk

filtration technology is used to remove from milk the water phase constituents which otherwise are removed when whey is separated from the cheese curd in traditional cheesemaking procedures. The use of filtered milk in standardized cheese enhances product consistency and production efficiencies, which yields cost savings that can be passed on to consumers. Milk filtration also allows for more efficient transportation of milk, which helps stabilize milk supplies. Because milk filtration removes the same water phase constituents that otherwise are removed from milk in the separation of "whey" from curd, the finished cheese has the same physical, chemical, and nutritional characteristics as cheese made from other forms of milk expressly permitted under existing standards. This petition proposes to amend section 133.3 of FDA regulations to recognize explicitly that filtered milk is encompassed within the definitions of "milk" and "nonfat milk," as used in Part 133 of FDA regulations, and may be used in reconstituted, concentrated, liquid, and dry forms in standardized cheese products like other forms of milk encompassed within the "milk" and "nonfat milk" definitions, to the extent permitted under applicable varietal cheese standards.

These amendments are consistent with the well-established and widespread use of milk filtration as part of the alternate make procedures for manufacturing standardized cheese, and would explicitly recognize that filtered milk products are interchangeable with other forms of milk for purposes of cheese manufacturing. Consistent with FDA's existing policy under section 133.3 concerning the forms of milk that may be used in cheesemaking, the amendments would encompass dry forms of filtered milk, allowing water to be further removed by evaporation. In addition, the amendments would extend the authorized use of filtered milk to cheese varieties subject to standards of identity that, for historical reasons, do not include

alternate make procedures, to the extent that filtered milk can feasibly be used under the traditional make procedures specified in these standards. The amendments also would facilitate administration of the cheese manufacturing plant inspection requirements associated with the USDA cheese grading service.

B. Action Requested

This petition requests that the Commissioner of Food and Drugs amend 21 C.F.R. § 133.3 (a) and (b) by adding the underscored language below specifying that "filtered milk" and "filtered skim milk" are acceptable forms of milk and nonfat milk respectively for use in standardized cheese and cheese products, and by adding a new subsection (c) as set forth below defining "filtered milk" for this purpose.

(a) *Milk* means the lacteal secretion, practically free from colostrum, obtained by the complete milking of one or more healthy cows, which may be clarified and may be adjusted by separating part of the fat therefrom; concentrated milk, filtered milk, reconstituted milk, and dry whole milk. Water, in a sufficient quantity to reconstitute concentrated and dry forms of milk, may be added.

(b) *Nonfat milk* means skim milk, concentrated skim milk, filtered skim milk, reconstituted skim milk, and nonfat dry milk. Water, in a sufficient quantity to reconstitute concentrated and dry forms of nonfat milk, may be added.

(c) *Filtered milk* means the milk product produced by a physical separation technique in which raw or pasteurized milk is passed over one or more semipermeable membranes to partially remove the water phase and its constituents, including water, lactose, whey proteins, and minerals. Either before or after filtration, fat may be separated to produce filtered skim milk. After filtration, water may be further removed by means of evaporation. Filtered milk can be used as a fluid, concentrate, or dry product. Water, in a sufficient quantity to reconstitute concentrated and dry forms, may be added.

See Attachment A.

C. Statement of Grounds

1. Introduction

FDA's standards of identity for most cheese and cheese products contain "alternate make procedure" provisions which expressly permit cheesemakers to use either the traditional cheese manufacturing process described in the standard or an alternate procedure that yields a finished cheese with the same physical and chemical properties. The standards in Part 133 that include alternate make procedure provisions are listed in Attachment B. The alternate make procedure provisions historically have enabled cheesemakers to embrace advances in cheese manufacturing technology that yield economic efficiencies and enhance quality while maintaining the character of cheese made using the traditional procedures. The alternate make procedure provisions have helped limit lengthy and expensive regulatory proceedings to amend the standards of identity for cheese to cover only those changes in cheese manufacturing procedures that produce a material change in the finished product. The alternate make procedure provisions have helped maintain the established high quality of standardized cheese while fostering the adoption of new technologies, including milk filtration. The extensive use of filtration technologies under the alternate make procedure provisions has produced significant benefits by improving product consistency and manufacturing efficiency, and expanding milk sourcing options enabling cheesemakers to respond more effectively to regional disruptions in the fluid milk supply, such as those caused by adverse weather conditions.

Although the petitioners believe that the alternate make procedure provisions of FDA's cheese standards provide an ample legal basis for the continued use of filtered milk in the manufacture of standardized cheese, we seek the proposed amendments to the definitions section

of Part 133 to recognize explicitly that filtered milk and filtered skim milk produced using mechanical filtration are encompassed by the terms "milk" and "nonfat milk" in section 133.3. We believe that these amendments are needed for two reasons. First, by explicitly recognizing filtered milk products as "milk" and "nonfat milk" for purposes of cheese manufacturing, the proposed amendments would allow cheese manufacturers to expand the use of filtration technologies and the resulting filtered milk in cheese manufacturing. The use of filtered milk would be permitted in standardized cheeses which are governed by standards of identity that, for historical reasons, do not include alternate make procedure provisions, to the extent feasible under the traditional make procedures specified in the existing standards. In addition, by treating filtered milk products consistently with FDA policy with respect to other forms of "milk" for cheese manufacturing under section 133.3, dry forms of filtered milk could be used, which would allow filtered milk to be shipped and stored to help manage seasonal imbalances in milk supplies and demand for cheese. This also would allow smaller cheese manufacturers, which do not always have direct or consistent access to milk filtration facilities, to buy and store dry forms of filtered milk according to demand. This would expand the range of cheese manufacturers able to achieve the production efficiencies offered by filtered milk and the resulting cost savings that ultimately could be passed on to consumers.

Second, the proposed amendments would assist the USDA Office of Dairy Programs in administering plant inspection requirements associated with its voluntary cheese grading service by specifying that filtered milk products are encompassed within the meanings of "milk" and "nonfat milk" as used in Part 133 and may be used in the manufacture of standardized cheese. The proposed amendments also would help USDA inspectors distinguish filtered milk

products used as ingredients in standardized cheeses from other milk isolates (such as chemically derived caseinates) that are produced through other separation processes which never have been encompassed by the alternate make procedure provisions for standardized cheeses.

2. The Use of Filtered Milk in Cheese Manufacturing

Mechanical filtration has been used extensively to process skim, reduced fat, and whole milk in cheese manufacturing in the United States for the past 20 years. We estimate that filtration techniques have been used to manufacture billions of pounds of cheese in the United States alone since this process was introduced. The history of use of milk filtration by European cheesemakers is even longer, predating its use by U.S. manufacturers by at least ten years. For many years, the International Dairy Federation (IDF) has promoted milk filtration as a basic process for cheesemaking internationally, holding numerous symposia to educate cheesemakers on the technology and use of filtered milk in cheese manufacturing.

In general, the term "mechanical filtration" describes one of several membrane filtration techniques used by the food industry. In filtration, a pressurized fluid stream is passed over a semipermeable membrane which separates the liquid into two effluent streams. The "permeate" is the water phase stream that has passed through the membrane, while the "retentate" is the solids stream that has not passed through the membrane. See Attachment C. The size of the pores in the membrane and the number of membranes the fluid is passed over determine the concentration (e.g., 2x to 6x) of the retentate and the proportion of the water phase that has been removed as permeate. The membrane pore sizes vary between .0001 and .20 microns. This confines the composition of the permeate to the water phase constituents of fluid

milk—the same constituents that otherwise would be removed as whey in the traditional cheesemaking process.

In traditional cheesemaking, water, lactose, protein, and ash (minerals) are removed from cheese curd in the form of whey through a draining procedure known as whey syneresis. Syneresis occurs at several steps in the cheese manufacturing process, resulting in a significant reduction in these constituents as compared to fluid milk. Similarly, in mechanical filtration, raw or pasteurized milk is separated into permeate, which consists of water and water soluble constituents including lactose, non-protein nitrogen, whey proteins, and ash; and retentate, which contains butterfat and casein in addition to the remaining water phase constituents. The retentate is used instead of or in combination with milk, nonfat dry milk, or cream to make cheese. See Attachment D.

Because mechanical filtration removes only those constituents that are removed by whey syneresis in traditional cheesemaking, it functions effectively to rearrange the steps in the cheesemaking process to permit the water phase constituents to be removed from fluid milk. To produce a cheese using filtered milk that is equivalent physically, chemically, and nutritionally to a cheese made using traditional procedures, there is no need to add back any constituent lost to the permeate in the filtration process. A cheese that conforms with the moisture and solids requirements of the applicable FDA standard is necessarily equivalent when made directly from filtered milk in simple combination with other dairy ingredients that are already specifically permitted under the standard. The long history and widespread use of filtration technology and the resulting filtered milk under the alternate make procedure provisions have clearly established the equivalence of standardized cheese made from filtered

milk and cheese made from other forms of milk already explicitly authorized under section 133.3. See Attachment F and pages 14-17, infra.

The ability of cheesemakers essentially to remove water phase constituents from fluid milk by means of mechanical filtration offers several distinct advantages. Cheesemakers are able to work with a smaller volume and more concentrated form of milk which facilitates standardization of formulation and production, promoting more consistent quality and yields. Since mechanical filtration is more effective than whey syneresis at retaining nutritionally valuable milk proteins, cheese yields may be greater in batches using filtered milk. This conservation of desirable proteins also results in a corresponding decrease in whey disposal costs.

Mechanical filtration operations in cheese manufacturing originally were based in the same plant as other steps in the cheese manufacturing process. However, the benefits of economies of scale increasingly have caused cheese processors to rely on centralized milk filtering operations.

Larger cheese manufacturers frequently are able to centralize mechanical filtration operations in a single plant supplying multiple manufacturing facilities. Milk may now be filtered at or near the raw milk source and the filtered milk shipped to other facilities for further processing at lower refrigeration and hauling costs. In addition, the lower hauling costs for filtered milk have enabled cheesemakers to source milk from more distant regions, enabling them to meet milk demands for cheese manufacturing more effectively, particularly when there are disruptions in regional fluid milk supplies from serious drought or other adverse conditions, as occurred during 1999.

Smaller companies can benefit from similar economies of scale through cooperative arrangements or contracts with third party suppliers of filtration services and filtered milk, including dairy farmers using filtration to concentrate raw milk at the farm. By removing additional water from fluid filtered milk through evaporation, smaller producers can realize even greater efficiencies by further reducing their hauling and storage costs. In addition, dry filtered milk can be stored by small cheese manufacturers who do not always have access to a consistent supply of fluid forms and who are disproportionately affected by seasonal supply imbalances.

Centralizing milk filtering operations, like centralizing cheese aging and shredding operations, allows manufacturers to realize processing efficiencies through lower hauling, capital equipment, and labor costs. These efficiencies create cost savings that can ultimately be passed on to consumers.

3. The NCI/GMA/NFPA Proposal Is Consistent with Established FDA Policy

The amendments proposed by NCI, GMA, and NFPA to formally recognize that filtered milk and nonfat milk are acceptable forms of milk and nonfat milk respectively for use in standardized cheese are entirely consistent with existing FDA policy. Most FDA standards of identity for natural cheeses contain alternate make procedure provisions which state that the cheese may be manufactured according to a specified traditional procedure or "by any other procedure which produces a finished cheese having the same physical and chemical properties." See 21 C.F.R. Part 133. See also Attachment B. The alternate make procedure provisions historically have provided the legal basis for the use of milk filtration and the resulting filtered milk in cheesemaking. Nothing in the alternate make procedure provisions requires that all cheesemaking procedures be accomplished in a single manufacturing facility or by a single firm.

Mechanical filtration of fluid milk is merely an interim step in the manufacture of cheese, regardless of whether such processing occurs in the same plant as other cheesemaking procedures or in a centralized filtration facility. In this regard, mechanical filtration is similar to spray-drying milk into a reconstitutable powder.

FDA has acknowledged that the use of mechanically filtered milk to manufacture Cheddar cheese is covered by the alternate make procedure provision of the Cheddar cheese standard, including when filtration occurs in a separate centralized facility. In a letter to a third party supplier of filtered milk, FDA stated:

> "Cheddar cheese is one of the standardized cheeses for which 'alternate make procedures' have been provided . . . . Under alternate make procedures, Cheddar cheese may be prepared by any procedure which produces a finished cheese having the same physical and chemical properties as the cheese prepared by the traditional cheesemaking process . . . . [I]t is our understanding that the Cheddar cheese produced from the retentate that results when milk is subjected to processing in an ultrafiltration system is nutritionally equivalent to and is physically and chemically identical to the Cheddar cheese prepared by the procedures set forth in the standard . . . . Based on this understanding, we would not object at this time to the use of this retentate in the manufacture of Cheddar cheese . . . ."

Letter from Dr. Margaret E. Cole, FDA Office of Food Labeling, to Mr. Ted Jacoby (October 21, 1996) (Attachment E). FDA's letter specifically recognized that, while "retentate is produced solely in-house by other companies as a step in the manufacture of various cheeses," the sale of retentate by one manufacturer to another for use in the manufacture of cheese "conforms with the requirements of the alternate make procedure."

The rationale stated in the FDA letter is consistent with the industry's longstanding position and supports the use of mechanical filtration in the manufacture of all

standardized cheeses produced using an alternate make procedure. To amend section 133.3 of the FDA cheese standards as the petitioners propose would effectively codify this policy and extend it to those cheeses that, for historical reasons, are subject to standards that lack alternate make procedure provisions. Formally recognizing that filtered milk products qualify as "milk" and "nonfat milk" for cheesemaking also is consistent with the policy underlying the earlier amendments to section 133.3 which recognized that "milk" and "nonfat milk" encompass forms of milk that function as alternatives to fluid milk in cheese manufacturing.

These amendments to section 133.3 authorized the use of alternate forms of milk, including concentrated, dry, and reconstituted forms, as substitutes for fluid milk in cheesemaking because these forms of milk may be used in place of fluid milk to produce a finished cheese that is equivalent physically and chemically to the traditional cheese made using fluid milk. The proposal specifically recognized the consistency of these amendments with the policy underlying the alternate make procedure provisions. The preamble to the 1978 proposed amendments states:

> "The existing cheese standards specify that the basic ingredient for cheese manufacture is fluid cow's milk which may have the fat of [sic] solids-not-fat levels adjusted by removing milkfat or adding cream, nonfat milk, concentrated skim milk or nonfat dry milk. The Commissioner believes that, technologically, alternate forms of milk, nonfat milk, and cream, i.e., concentrated, dried, and reconstituted forms, can be used to produce the same cheese as produced from fluid cow's milk. Further, he is of the opinion that provision for alternate forms of these milk products would be consistent with the provision in the existing standards for alternate manufacturing procedures that do not adversely affect the physical and chemical properties of the cheese. . . . While cheese must contain forms of milk, nonfat milk or cream, the manufacturer has the option of choosing, within specific classes of milk products, those forms he prefers to use."

43 Fed. Reg. 42127, 42128 (1978); see also 21 C.F.R. § 133.3(a) (specifying that "milk" includes concentrated, reconstituted, and dry forms). The amendments the petitioners propose to section 133.3 with respect to filtered milk are fully consistent with the basis and rationale for these earlier amendments expanding the scope of forms of milk recognized as "milk" for cheesemaking.

The flexible approach FDA has taken to allow alternate forms of milk to be treated interchangeably under section 133.3 where they can be used in accordance with the applicable standard to yield an equivalent finished cheese is consistent with the broader policy to recognize the comparable functionality of dairy ingredients, including those made by mechanical filtration, in dairy foods. FDA's standards of identity for dairy products permit manufacturers to use modified whey products, including mechanically-filtered whey in the form of whey protein concentrate, instead of milk, so long as such use does not materially affect the total nonfat milk solids content of the food. See, e.g., 46 Fed. Reg. 44432 (1981); 21 C.F.R. § 135.110(b) (ice cream and frozen custard); 21 C.F.R. § 131.200(d) (yogurt). Whey protein concentrate is made by physically separating the minerals, lactose, and water from whey through filtration. See 21 C.F.R. § 1979c. This is essentially the same process used to make filtered milk.

FDA's food labeling regulations also acknowledge the interchangeability of dairy ingredients. FDA's general food labeling regulations specify that the generic term "milk" may be used in ingredient labeling rather than the more specific terms, "concentrated milk," "reconstituted milk," and "dry whole milk." See 21 C.F.R. § 101.4(b)(4). Moreover, in amending the cheese standards to permit alternate milk ingredients, FDA stood by its generic labeling policy, rejecting comments suggesting that the alternate milk forms be listed by specific

name. FDA justified its approach emphasizing that "differences in the form of the dairy ingredients used . . . have no perceptible effect on the final [cheese] product." See 48 Fed. Reg. 2736, 2738 (1983).

4. Cheese Made With Filtered Milk Is Nutritionally Equivalent To Traditional Cheese

Cheese made using filtered milk is nutritionally equivalent to cheese made using other forms of "milk" or "nonfat milk" already recognized in section 133.3. FDA regulations specify that a food is "nutritionally inferior" to the reference food when there is "any reduction in the content of an essential nutrient that is present in a measurable amount" compared with the reference food. See 21 C.F.R. § 101.3(e)(4)(i). A "measurable" reduction is defined as two percent or more of the Daily Value of the essential nutrient for the finished product. See 21 C.F.R. § 101.3(e)(4)(ii). See also 61 Fed. Reg. 58991, 58997 (1996) ("foods having significantly less essential nutrients" are nutritionally inferior). Mechanical filtration of milk using membranes with pore sizes between .0001 and .20 microns removes the water phase constituents, which otherwise would be removed in the traditional cheesemaking process as whey. Milk consists of a solid phase (fat and colloidal protein) and a water phase (water, soluble protein, lactose, minerals, and some water soluble vitamins). In traditional cheesemaking, the fat and the colloidal protein coagulate, resulting in almost 100 percent retention of these components in the cheese and significant loss of the water phase constituents in the form of whey. By filtering milk with membranes, cheese manufacturers can remove the constituents of the water phase in the same proportion as these constituents would otherwise be removed in whey. As a result, the cheese produced using filtered milk is nutritionally equivalent to cheese made using other forms of milk.

Notably, under FDA regulations, nutritional variations that involve an increase in essential nutrients relative to the reference food do not render the modified food nutritionally inferior. Such increases are acceptable provided they are disclosed in nutrition labeling. See 21 C.F.R. § 101.9(c), (g). With respect to filtered milk in cheese, the retentate may actually contain slightly greater concentrations of valuable constituents (e.g., whey proteins) than the cheese curd that remains after syneresis in traditional cheesemaking. Under existing FDA policy, cheese made with filtered milk is not "nutritionally inferior" to cheese made using traditional procedures, and any material increases in nutritional value in the finished cheese (e.g., protein content) would be reflected in nutritional labeling.

Indeed, cheeses made using even relatively large quantities of filtered milk exhibit the same natural variations in moisture, protein, fat, and ash content as cheeses made using traditional procedures. Two large cheese manufacturers have undertaken extensive research comparing the concentrations of protein, total fat, and key vitamins and minerals in Cheddar cheese made using filtered milk with those in Cheddar cheese made using traditional procedures. Data from these studies indicate that Cheddar cheese made from filtered milk contains protein, fat, and key vitamins and minerals in concentrations that lie squarely within the range exhibited naturally in Cheddar cheese made using traditional procedures. Similarly, data published in 1981 from 14 experiments demonstrate that the mean concentrations of key constituents (fat, calcium, phosphorus, and protein) in hard cheeses made from filtered milk also were within the range permitted by USDA standards. See Attachment F.

The data supporting the nutritional equivalence of Cheddar cheese made with filtered milk with traditional versions is extensive, and represents a category of cheese for which

any potential opportunity for filtered milk to affect nutritional quality would be greatest. First, filtered milk is used in Cheddar cheese under alternate make procedures, which means the cheese can be formulated with a significant proportion of filtered milk, and an amount substantial enough to display nutritional inferiority, if that would result from the use of filtered milk. Second, the Cheddar cheese standard specifies that the finished cheese must have a moisture content that is relatively low compared to other varieties. See 21 C.F.R. § 133.113(a)(1). This means that Cheddar cheese can readily be made with significant amounts of the more concentrated forms of filtered milk (e.g., 6x), in which nutrient losses in the water phase would be greatest because of the greater proportion of the water phase constituents removed through filtration. The data demonstrating the nutritional equivalence of Cheddar cheese made from filtered milk with traditional Cheddar cheese lend strong support for the nutritional equivalence of cheeses made from filtered milk generally.

Moreover, the nutritional equivalence of standardized cheese made with filtered milk to traditional cheese is assured by the limitations imposed on the use of filtered milk by the make procedures and ingredients already specified in the cheese standards. First, for cheeses for which alternate make procedures are not permitted, the rigid parameters of the traditional make procedures themselves, coupled with the moisture and solids requirements and other specifications, sharply limit the amount of filtered milk that could be used under the proposed amendments and assures that the use of filtered milk would have no material effect on the nutrient levels of the finished cheese.

Second, for those cheese varieties subject to standards which include alternate make procedure provisions and in which filtered milk can be used in more significant amounts,

the alternate make procedure provisions themselves provide that cheese made using an alternate procedure must be physically and chemically equivalent to cheese made using the traditional procedure. See, e.g., 21 C.F.R. § 133.113(a) (stating that cheese may be manufactured under the traditional make procedure or "any other procedure which produces a finished cheese having the same physical and chemical properties."). Under existing FDA policy, the requirement that a cheese have the same "chemical properties" encompasses those chemical entities with nutritional value, and thus requires nutritional equivalence. See, e.g., supra page 11 (excerpt of letter from Dr. Margaret Cole, FDA Office of Food Labeling). The proposed amendments would make no change in this nutritional equivalence requirement. Under the proposed amendments, filtered milk in any form could only be used to the extent the finished cheese is nutritionally equivalent to cheese made under the traditional procedure .

5. The NCI/GMA/NFPA Proposal Is Consistent With The Codex Standard For Cheese

Consistent with section 410(c) of the FDA Modernization Act of 1997 (codified at 21 U.S.C. § 383(c)) and FDA's international harmonization policy (60 Fed. Reg. 53078 (1995)), it has been an FDA priority to promote international harmonization of regulatory requirements, including through FDA participation in the activities of the Codex Alimentarius Commission relating to food standards. The Codex standard of identity for cheese, Standard A-6-1978 (revised in January 1999), provides:

> "Cheese is the ripened or unripened soft or semi-hard, hard and extra hard product, which may be coated, and in which the whey protein-casein ratio does not exceed that of milk, obtained by:
>
> (a) coagulating wholly or partly the following raw materials: milk and/or products obtained from milk,

through the action of rennet or other suitable coagulating agents, and by partially draining the whey resulting from such coagulation; and/or

(b) processing techniques involving coagulation of milk and/or products obtained from milk which give an end-product with similar physical, chemical and organoleptic characteristics as the product defined under (a)."

The Codex standard also provides that cheese must contain "milk and/or products obtained from milk." Under Codex Standard 206-1999, a "milk product" is "a product obtained by any processing of milk . . ." (emphasis added). The Codex standard encompasses mechanical filtration technology, provided the finished cheese meets applicable requirements for physical and chemical properties, which would include nutritional and organoleptic properties. The petitioners' proposal thus is consistent with FDA efforts aimed at international harmonization of cheese standards.

6. The Proposal Would Advance President Clinton's "Reinventing Government" Initiative

On March 4, 1995, as part of the Administration's "Reinventing Government" initiative, President Clinton issued a memorandum directing agencies to take four steps designed to improve the federal regulatory system. See Memorandum on Regulatory Reform, 31 WEEKLY COMP. PRES. DOC. 363 (March 6, 1995). The President noted that, while all Americans want the benefits of effective regulation, too often federal regulations are drafted with unnecessary restrictions that undermine the objectives they seek to achieve. In response to the initiative, FDA identified food standards as prime candidates for reform because of their "potential to limit technological advances," and endorsed the notion that food manufacturers should have greater

flexibility to adopt new technologies so long as the character of the finished standardized food remains the same:

> "[T]he agency recognizes that food standards may serve as an impediment to the food industry to the degree to which they fail to reflect advances in food science and technology. New ingredients and plant varieties that allow manufacturers to enhance a food's organoleptic or functional properties, alter its nutritional profile, or extend its shelf life, are being developed and used in nonstandardized food products. Incorporation of these advances into standardized foods may be difficult or impossible without laborious amendment of the relevant standard. FDA believes that manufacturers of standardized foods should have the ability to make use of advances in food technology, provided the basic nature of the food remains essentially the same."

See 60 Fed. Reg. 67492, 67499 (1995).

In recent years, FDA has made a number of amendments to food standards to give manufacturers greater flexibility to take advantage of new technologies and expand ingredient options. See, e.g., 21 C.F.R. § 130.10 (establishing a "generic" standard of identity for nutritionally modified foods and authorizing expanded processing methods and ingredients); 59 Fed. Reg. 47072, 47077 (1994) (amending ice cream standard to permit lactose reduction by new technologies); 57 Fed. Reg. 23989 (1992) (amending standards of identity for chocolate products to permit use of any "safe and suitable" optional ingredient in a functional category).

The amendments proposed by NCI, GMA, and NFPA are consistent with the standards reform objectives articulated by FDA under the "Reinventing Government" initiative. The proposed amendments would facilitate the continued adoption of milk filtration technology in cheese manufacturing, enabling manufacturers to produce standardized cheese that is equivalent physically, chemically, and nutritionally to cheese made with the milk ingredients already listed in section 133.3, while gaining economic benefits of filtration technology.

E. Certification

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioners which are unfavorable to the petition.

F. Conclusion

For the foregoing reasons, we request that the agency adopt the amendments to section 133.3 proposed by NCI, GMA, and NFPA.

Respectfully submitted,

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A

Existing 21 C.F.R. § 133.3 Definitions.

(a) *Milk* means the lacteal secretion, practically free from colostrum, obtained by the complete milking of one or more healthy cows, which may be clarified and may be adjusted by separating part of the fat therefrom; concentrated milk, reconstituted milk, and dry whole milk. Water, in a sufficient quantity to reconstitute concentrated and dry forms, may be added.

(b) *Nonfat milk* means skim milk, concentrated skim milk, reconstituted skim milk, and nonfat dry milk. Water, in a sufficient quantity to reconstitute concentrated and dry forms, may be added.

(c) *Cream* means cream, reconstituted cream, dry cream, and plastic cream. Water, in a sufficient quantity to reconstitute concentrated and dry forms, may be added.

(d) *Pasteurized* when used to describe a dairy ingredient means that every particle of such ingredient shall have been heated in properly operated equipment to one of the temperatures specified in the table of this paragraph and held continuously at or above that temperature for the specified time (or other time/temperature relationship which has been demonstrated to be equivalent thereto in microbial destruction):

Temperature	Time
145 °F[1]	30 min.
161 °F[1]	15 s.
191 °F	1 s.
204 °F	0.05 s.
212 °F	0.01 s.

[1]If the dairy ingredient has a fat content of 10 percent or more, the specified temperature shall be increased by 5 °F.

(e) *Ultrapasteurized* when used to describe a dairy ingredient means that such ingredient shall have been thermally processed at or above 280 °F for at least 2 seconds.

Proposed 21 C.F.R. § 133.3 Definitions.

(a) *Milk* means the lacteal secretion, practically free from colostrum, obtained by the complete milking of one or more healthy cows, which may be clarified and may be adjusted by separating part of the fat therefrom; concentrated milk, filtered milk, reconstituted milk, and dry whole milk. Water, in a sufficient quantity to reconstitute concentrated and filtered forms, including dry forms of milk, may be added.

(b) *Nonfat milk* means skim milk, concentrated skim milk, filtered skim milk, reconstituted skim milk, and nonfat dry milk. Water, in a sufficient quantity to reconstitute concentrated and dry forms of nonfat milk, may be added.

(c) *Filtered milk* means the milk product produced by a physical separation technique in which raw or pasteurized milk is passed over one or more semipermeable membranes to partially remove the water phase and its constituents, including water, lactose, whey proteins, and minerals. Either before or after filtration, fat may be separated to produce filtered skim milk. After filtration, water may be further removed by means of evaporation. Water, in a sufficient quantity to reconstitute concentrated and dry forms, may be added.

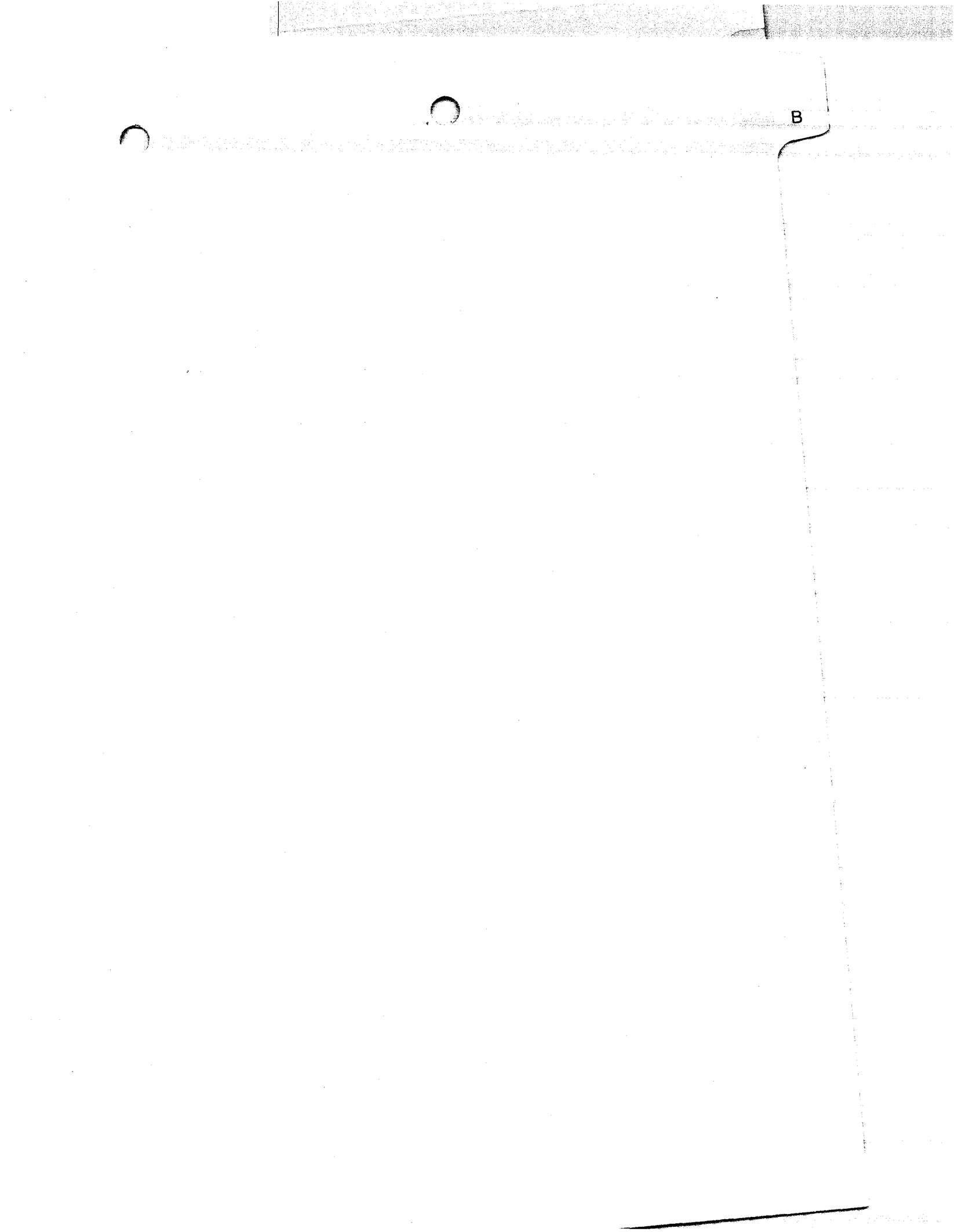
(d) *Cream* means cream, reconstituted cream, dry cream, and plastic cream. Water, in a sufficient quantity to reconstitute concentrated and dry forms, may be added.

(e) *Pasteurized* when used to describe a dairy ingredient means that every particle of such ingredient shall have been heated in properly operated equipment to one of the temperatures specified in the table of this paragraph and held continuously at or above that temperature for the specified time (or other time/temperature relationship which has been demonstrated to be equivalent thereto in microbial destruction):

Temperature	Time
145 °F[1]	30 min.
161 °F[1]	15 s.
191 °F	1 s.
204 °F	0.05 s.
212 °F	0.01 s.

[1]If the dairy ingredient has a fat content of 10 percent or more, the specified temperature shall be increased by 5 °F.

(f) *Ultrapasteurized* when used to describe a dairy ingredient means that such ingredient shall have been thermally processed at or above 280 °F for at least 2 seconds.


B

LIST OF FDA CHEESE STANDARDS WITH AND WITHOUT ALTERNATE MAKE PROCEDURE PROVISIONS

The standards of identity for the following cheeses provide for alternate make procedures:

1. § 133.102 Asiago fresh and asiago soft cheese
2. § 133.103 Asiago medium cheese
3. § 133.104 Asiago old cheese
4. § 133.106 Blue cheese
5. § 133.108 Brick cheese
6. § 133.109 Brick cheese for manufacturing
7. § 133.111 Caciocavallo siciliano cheese
8. § 133.113 Cheddar cheese
9. § 133.114 Cheddar cheese for manufacturing
10. § 133.116 Low sodium cheddar cheese
11. § 133.118 Colby cheese
12. § 133.119 Colby cheese for manufacturing
13. § 133.121 Low sodium colby cheese
14. § 133.127 Cook cheese, koch kaese
15. § 133.133 Cream cheese
16. § 133.136 Washed curd and soaked curd cheese
17. § 133.137 Washed curd cheese for manufacturing
18. § 133.138 Edam cheese
19. § 133.140 Gammelost cheese
20. § 133.141 Gorgonzola cheese
21. § 133.142 Gouda cheese
22. § 133.144 Granular and stirred curd cheese
23. § 133.145 Granular cheese for manufacturing
24. § 133.149 Gruyere cheese
25. § 133.152 Limburger cheese
26. § 133.153 Monterey cheese and monterey jack cheese
27. § 133.154 High-moisture jack cheese

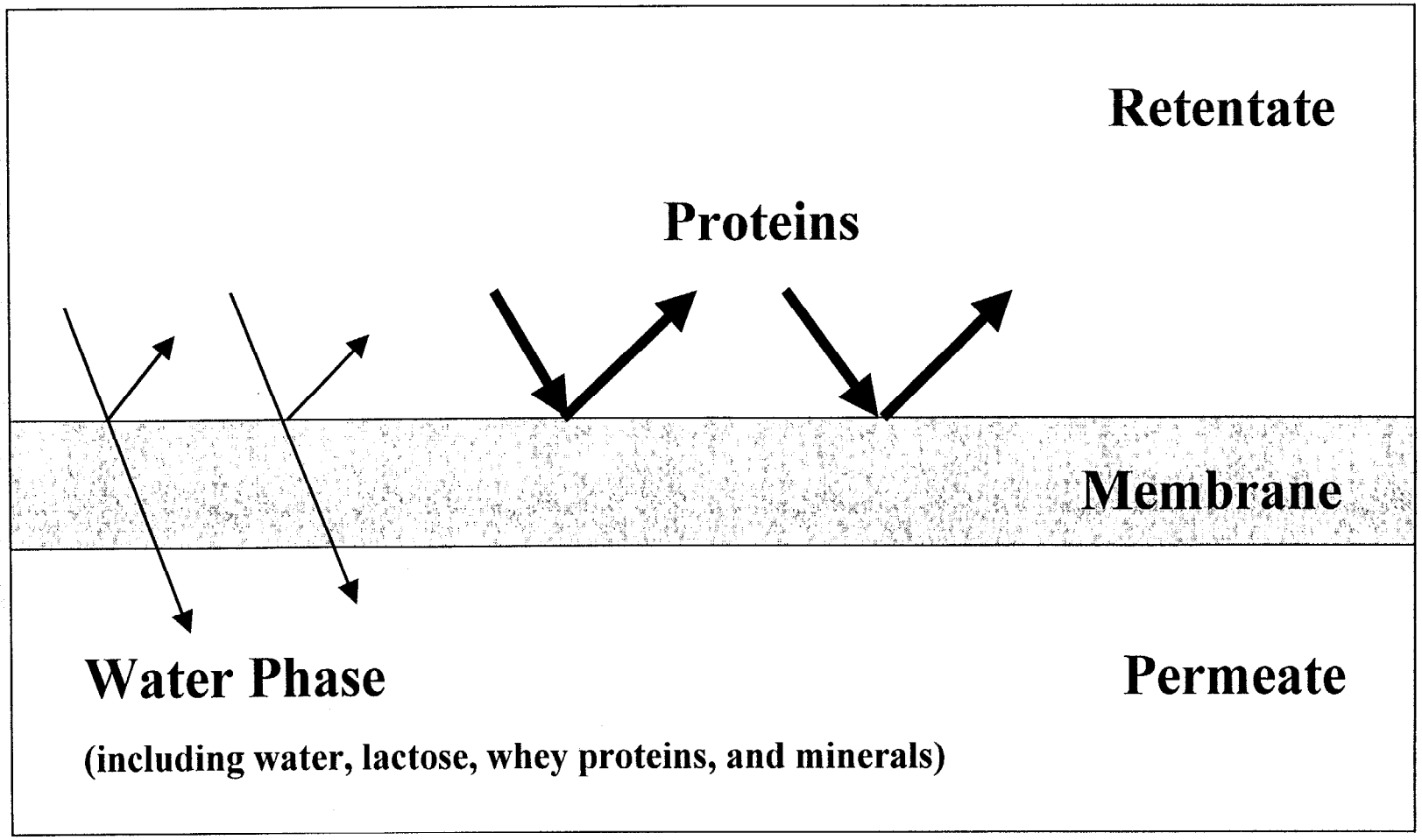
28. § 133.155 Mozzarella cheese and scamorza cheese
29. § 133.156 Low-moisture mozzarella and scamorza cheese
30. § 133.157 Part-skim mozzarella and scamorza cheese
31. § 133.158 Low-moisture part-skim mozzarella and scamorza cheese
32. § 133.160 Muenster and munster cheese
33. § 133.161 Muenster and munster cheese for manufacturing
34. § 133.162 Neufchatel cheese
35. § 133.164 Nuworld cheese
36. § 133.165 Parmesian and reggiano cheese
37. § 133.181 Provolone cheese
38. § 133.183 Romano cheese
39. § 133.184 Roquefort cheese, sheep's milk blue-mold, and blue-mold cheese from sheep's milk
40. § 133.185 Samsoe cheese
41. § 133.186 Sap sago cheese
42. § 133.189 Skim milk cheese for manufacturing
43. § 133.190 Spiced cheeses
44. § 133.191 Part-skin spiced cheeses
45. § 133.195 Swiss and emmentaler cheese
46. § 133.196 Swiss cheese for manufacturing

The standards of identity for the following cheeses do not provide for alternate make procedures:

1. § 133.123 Cold-pack and club cheese
2. § 133.125 Cold-pack cheese food with fruits, vegetables, or meats
3. § 133.128 Cottage cheese
4. § 133.129 Dry curd cottage cheese
5. § 133.134 Cream cheese with other foods
6. § 133.146 Grated cheeses
7. § 133.147 Grated American cheese food
8. § 133.148 Hard grating cheeses
9. § 133.150 Hard cheeses

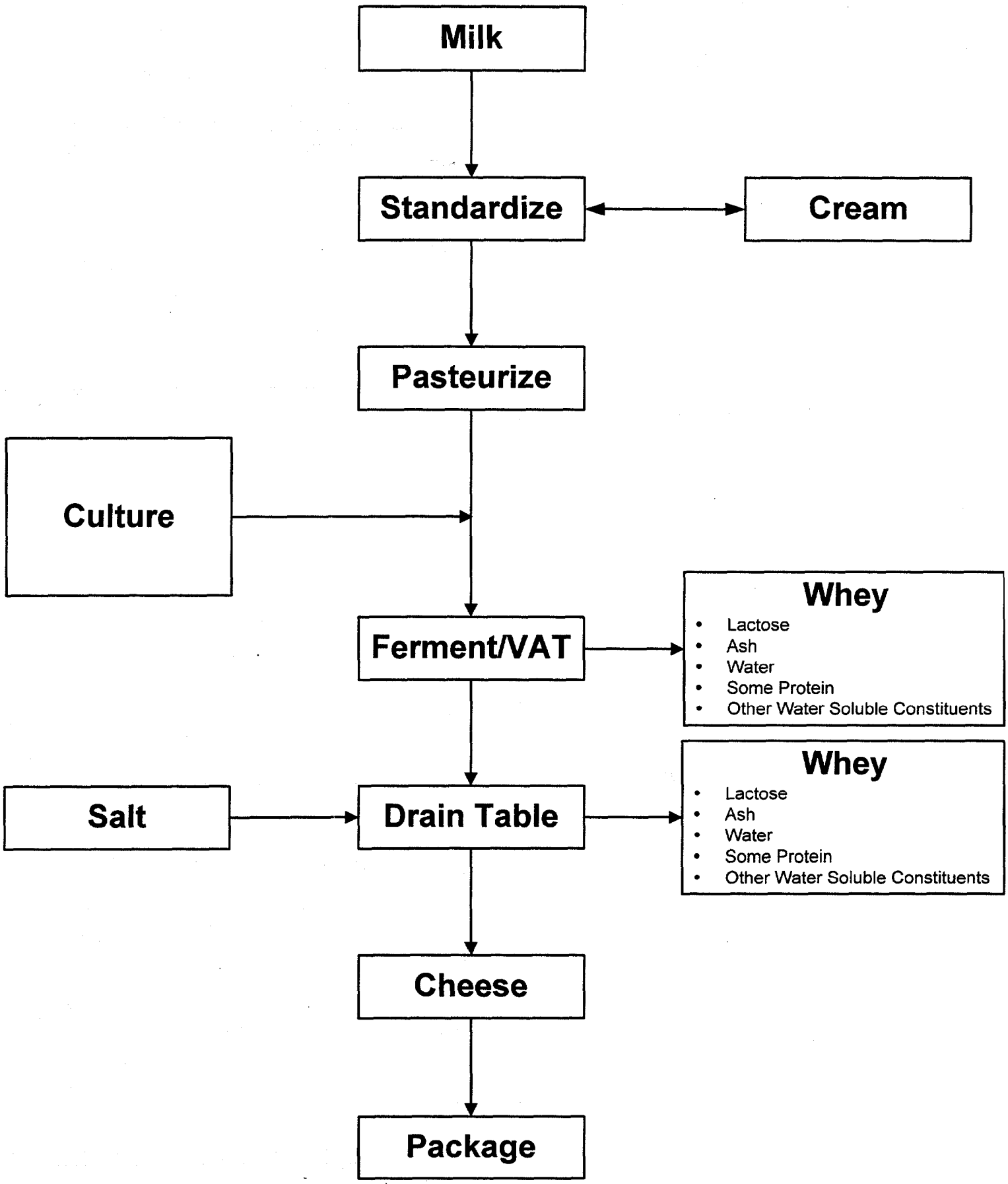
10. § 133.167 Pasteurized blended cheese
11. § 133.168 Pasteurized blended cheese with fruits, vegetables, or meats
12. § 133.169 Pasteurized process cheese
13. § 133.170 Pasteurized process cheese with fruits, vegetables, or meats
14. § 133.171 Pasteurized process pimento cheese
15. § 133.173 Pasteurized process cheese food
16. § 133.174 Pasteurized process cheese food with fruits, vegetables, or meats
17. § 133.175 Pasteurized cheese spread
18. § 133.176 Pasteurized cheese spread with fruits, vegetables, or meats
19. § 133.178 Pasteurized neufchatel cheese spread with other foods
20. § 133.179 Pasteurized process cheese spread
21. § 133.180 Pasteurized process cheese spread with fruits, vegetables, or meats
22. § 133.182 Soft ripened cheeses
23. § 133.187 Semisoft cheeses
24. § 133.188 Semisoft part-skim cheeses
25. § 133.189 Skim milk cheese for manufacturing
26. § 133.193 Spiced, flavored standardized cheeses

Filtration

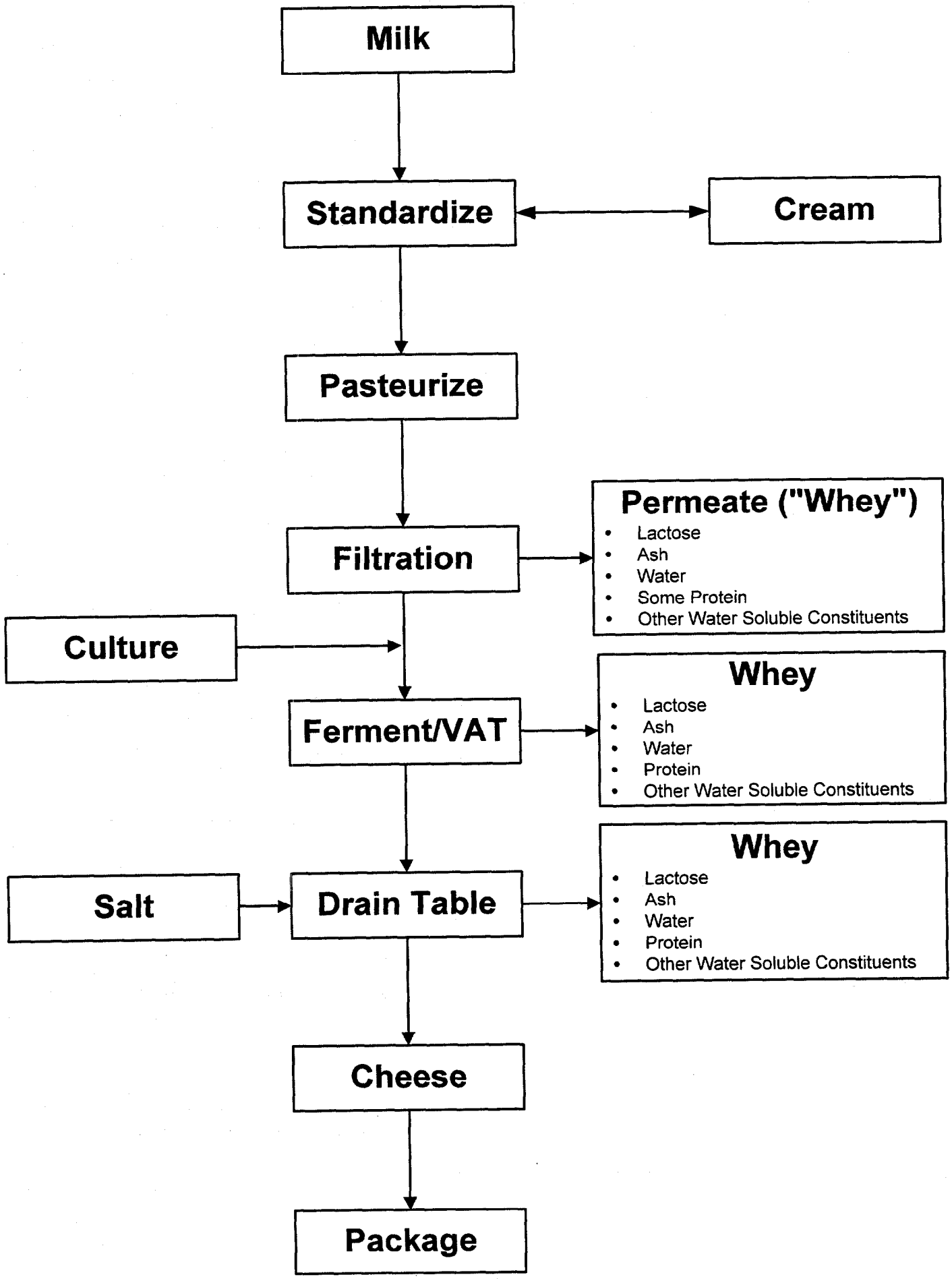

Retentate
Proteins
Membrane
Water Phase
Permeate
(including water, lactose, whey proteins, and minerals)

D

Traditional Cheese Manufacture



Cheese Manufacture/Filtered Milk



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington DC 20204

OCT 21 1996

Mr. Ted Jacoby, Jr.
T.C. Jacoby & Company, Inc.
3701 South Lindbergh Boulevard
St. Louis, Missouri 63127

Dear Mr. Jacoby:

This letter is in response to your correspondence, dated May 1, 1996, to Ms. Elizabeth J. Campbell, Director, Division of Programs and Enforcement Policy, Office of Food Labeling, and your subsequent meeting on August 27, 1996, to discuss the following issues: (1) the labeling of the dairy derived product which results when milk is subjected to processing in an ultrafiltration system and (2) the labeling of cheese that is made from an ultrafiltered milk product.

You refer to the ultrafiltered milk product that results from subjecting milk to processing in an ultrafiltration system and that is subsequently used for processing into cheese as the "retentate." Because some lactose, water, minerals, and water-soluble vitamins are removed from the milk by processing the milk in an ultrafiltration system, this retentate contains higher concentrations of protein, fat, and lactose and lower concentrations of minerals and water-soluble vitamins than milk. You state that the firm Bongards Creamery, Bongards, Minnesota, wishes to use this retentate in the manufacture of Cheddar cheese. You further indicated that retentate is produced solely in-house by other companies as a step in the manufacture of various cheeses.

We recognize that cheesemaking technology has changed tremendously in the last 30 years. Cheddar cheese is one of the standardized cheeses for which "alternate make procedures" have been provided under 21 CFR 133.113(a)(1). Under alternate make procedures, Cheddar cheese may be prepared by any procedure which produces a finished cheese having the same physical and chemical properties as the cheese prepared by the traditional cheese making process (i.e., the procedures set forth in the standard under 21 CFR 133.113(a)(3)).

From the information that you provided us, it is our understanding that the Cheddar cheese produced from the retentate that results when milk is subjected to processing

in an ultrafiltration system is nutritionally equivalent to and is physically and chemically identical to the Cheddar cheese prepared by the procedures set forth in the standard under 21 CFR 133.113(a)(3). Based on this understanding, we would not object at this time to the use of this retentate in the manufacture of Cheddar cheese by Bongards Creamery on the limited basis described in your May 1, 1996, correspondence. However, if it is found that the resultant cheese differs from that produced traditionally, use of the retentate in the cheese would necessitate a petition to amend the definition and standard of identity for the cheese.

Additionally, we are of the opinion at this time that the retentate that results when milk is subjected to processing in an ultrafiltration system may be declared as "milk" in the ingredient statement on the label of the Cheddar cheese produced at Bongards Creamery, provided that the Cheddar cheese manufactured from this retentate is at least nutritionally equivalent to and has the same physical and chemical properties, as the cheese prepared by the procedures specifically set forth in the applicable standard. However, we do not consider the term "milk" unqualified to be an appropriate ingredient declaration for the retentate produced by an ultrafiltration system, when it is used in food products, other than the standardized cheeses such as Cheddar cheese for which alternative make procedures have been specifically provided in the regulations.

Further, while in interstate commerce, the retentate is subject to the applicable requirements of the Federal Food, Drug, and Cosmetic (FD&C) Act and the regulations promulgated under the authority of the Act, and in addition, it must comply with applicable requirements of the Grade "A" Pasteurized Milk Ordinance (PMO) (1995 Revision). We remind you that Section 4 of the PMO requires that each shipment of the retentate be accompanied by a shipping statement that contains the name of the product, in compliance with the applicable requirements of the FD&C Act and regulations promulgated under the authority of the Act. As you are aware, the retentate does not meet the requirements of the definition and standard of identity for milk in 21 CFR 131.110; therefore, the retentate may not be labeled with the term "milk" unqualified. While we would not object to use of the term "milk" as a part of the name given to the retentate, the retentate needs to be labeled with an appropriately descriptive name that accurately reflects its true identity and is not false or misleading. We caution you that this name must clearly distinguish the retentate from the standardized food milk in terms of all salient characteristics (nutritional value, chemical composition, etc.), and the retentate must be labeled so that the

purchaser can readily determine how the retentate differs from milk.

We hope that this information is helpful.

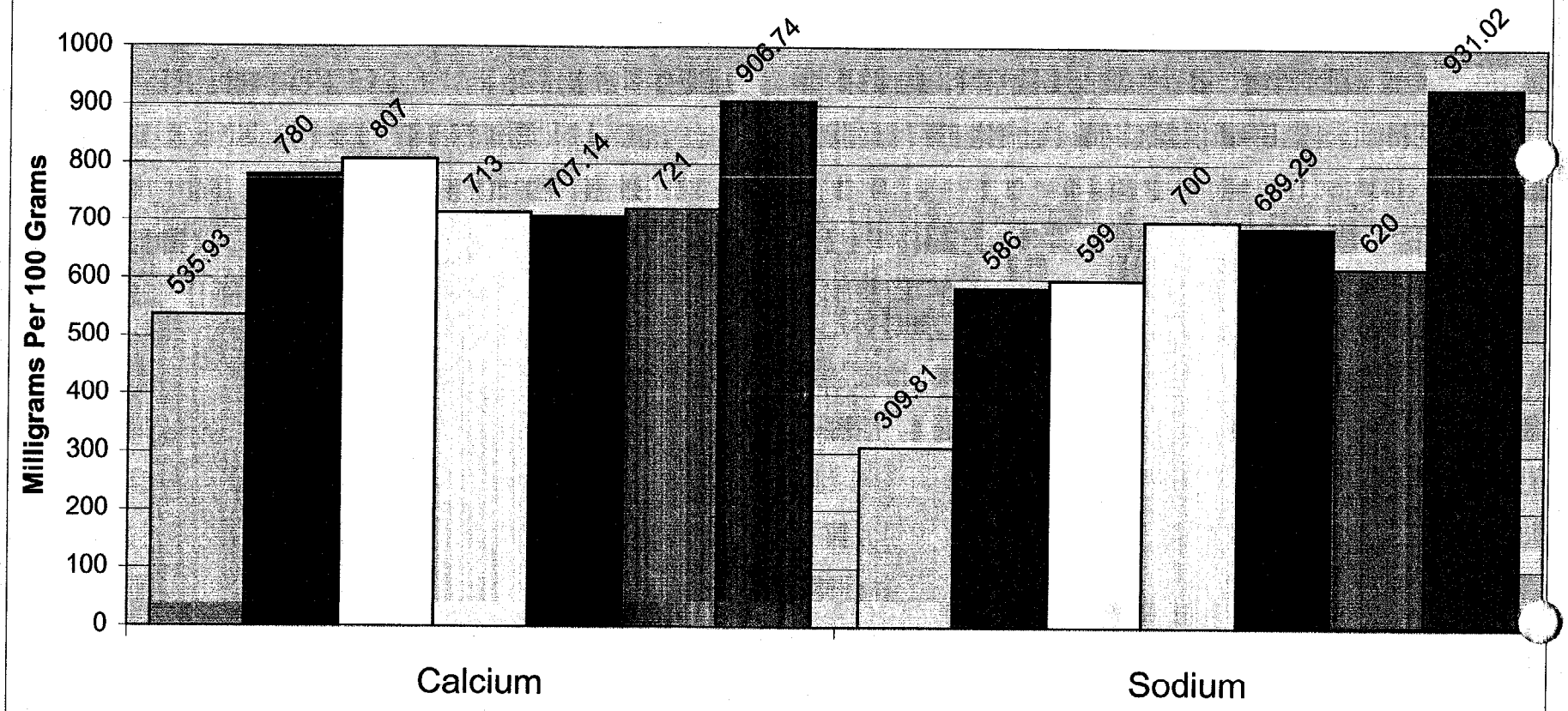
Sincerely yours,

Margaret E. Cole

Margaret E. Cole, Ph.D.
Division of Programs and
Enforcement Policy
Office of Food Labeling

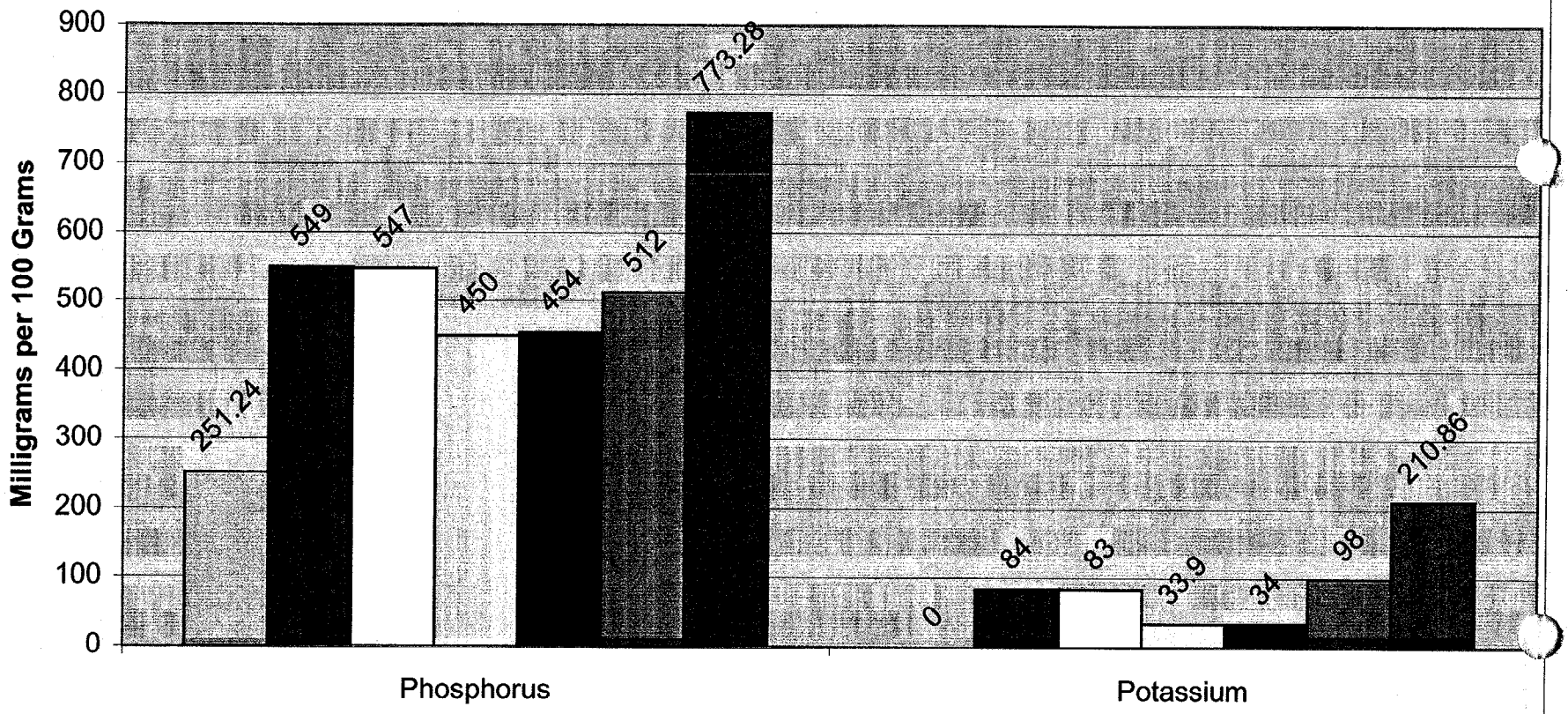
S OFFICE PRODUCTS

Samples of Cheddar Cheese Made from Filtered Milk Compared to USDA and US Range Values*



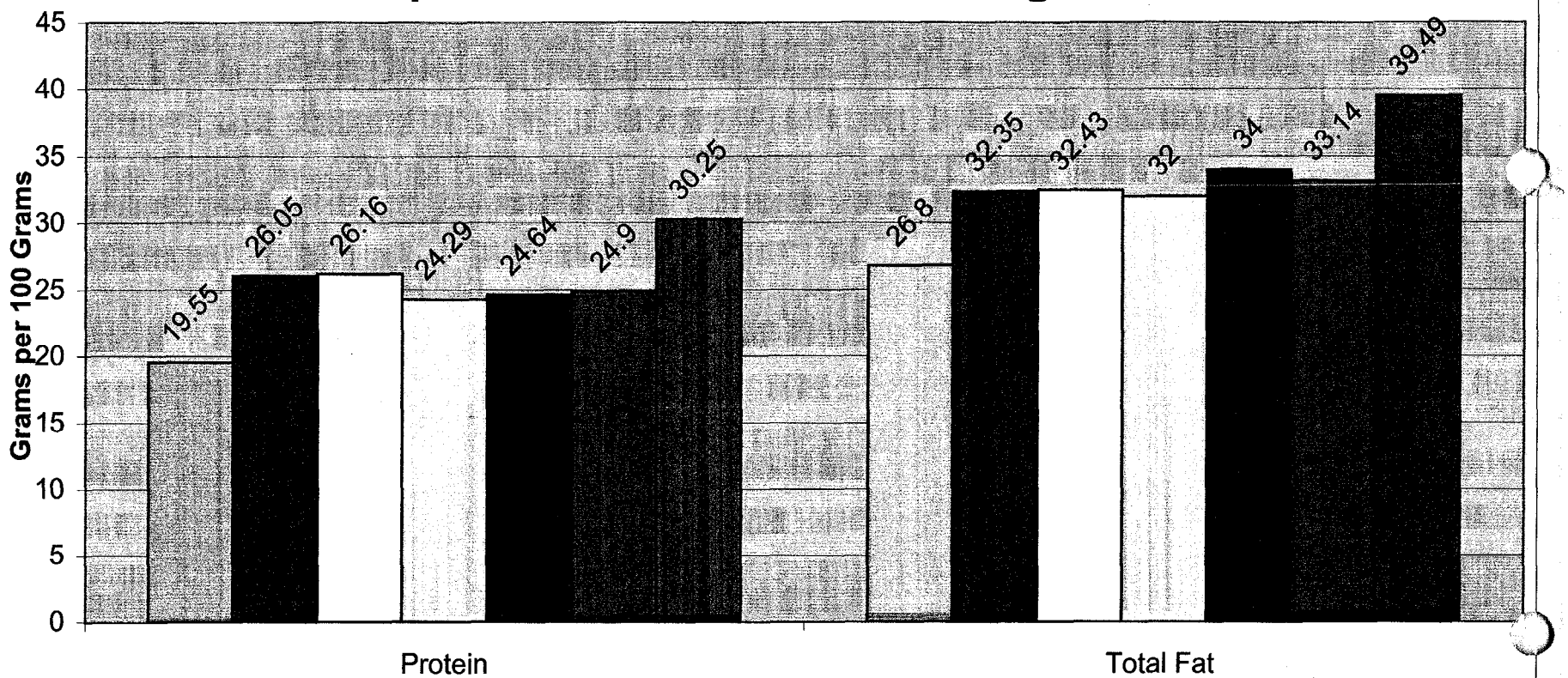
* 3 standard deviations from USDA Handbook 8-1values

Samples of Cheddar Cheese Made from Filtered Milk Compared to USDA and US Range Values*

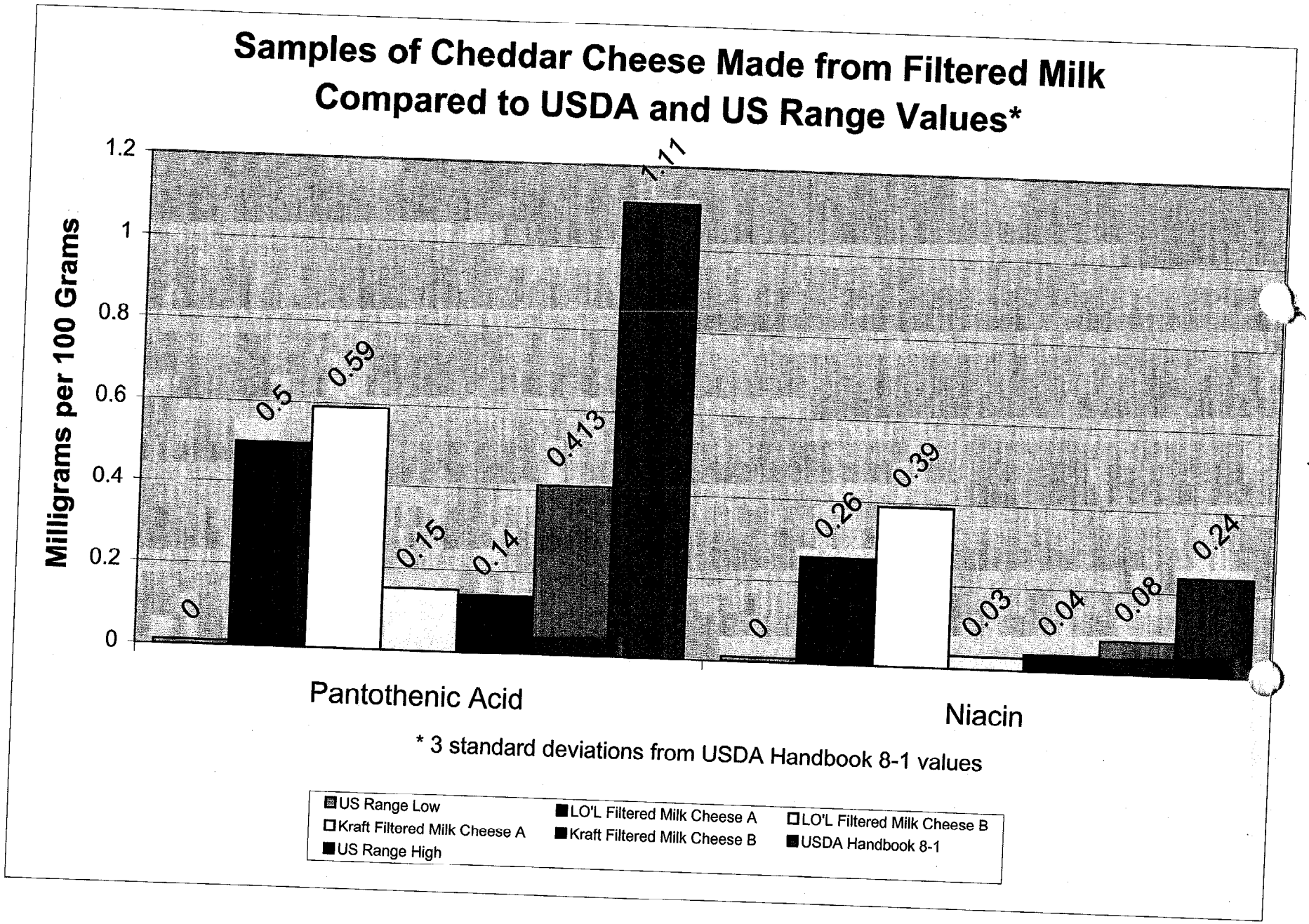


* 3 standard deviations from USDA Handbook 8-1 values

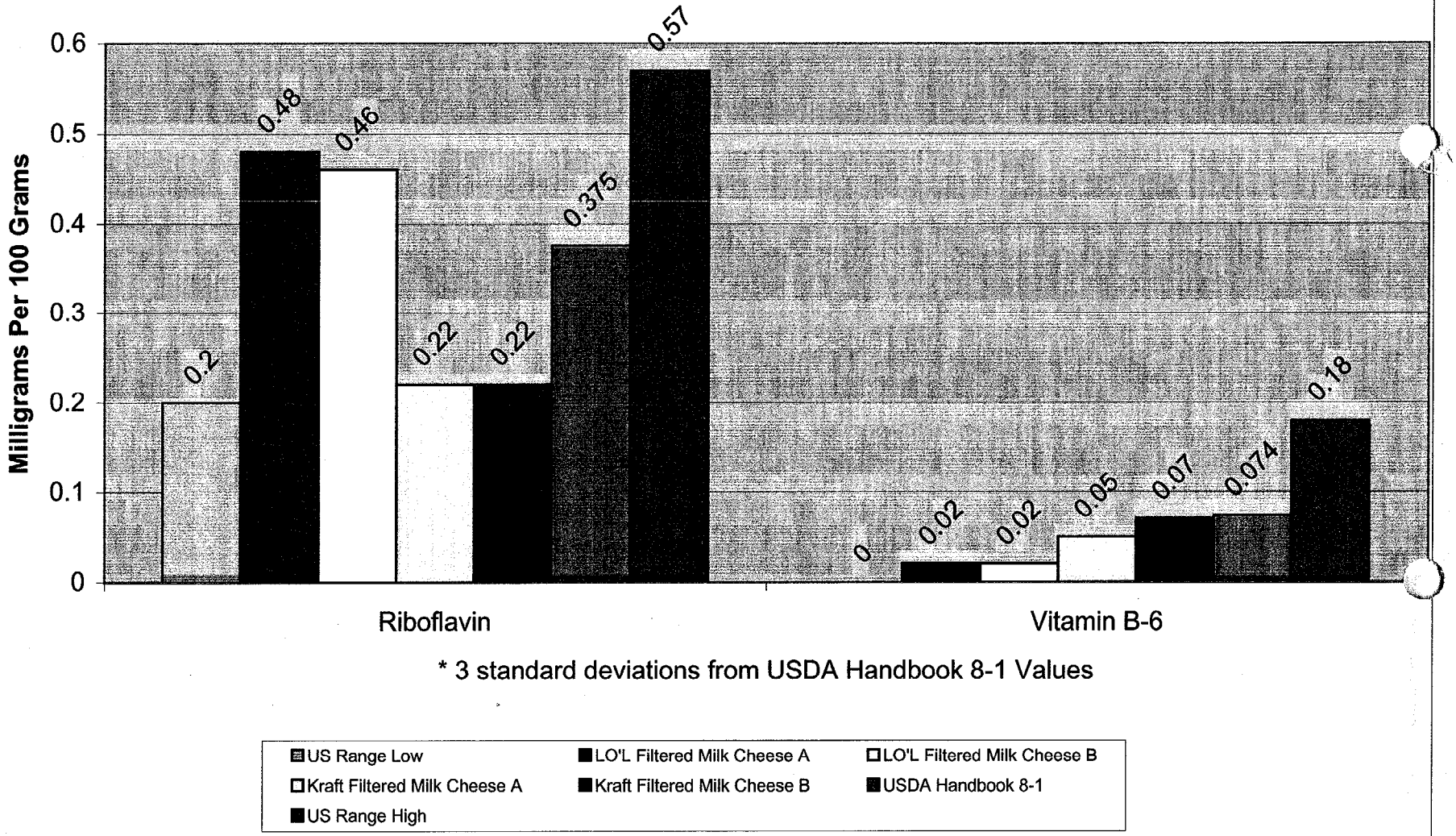
Samples of Cheddar Cheese Made from Filtered Milk Compared to USDA and US Range Values*



* 3 standard deviations from USDA Handbook 8-1 Values


Samples of Cheddar Cheese Made from Filtered Milk
Compared to USDA and US Range Values*
Milligrams per 100 Grams
1.2
1
0.8
0.6
0.4
0.2
0
0
0.5
0.59
0.15
0.14
0.413
1.11
0
0.26
0.39
0.03
0.04
0.08
0.24
Pantothenic Acid
Niacin
* 3 standard deviations from USDA Handbook 8-1 values
US Range Low
LO'L Filtered Milk Cheese A
LO'L Filtered Milk Cheese B
Kraft Filtered Milk Cheese A
Kraft Filtered Milk Cheese B
USDA Handbook 8-1
US Range High

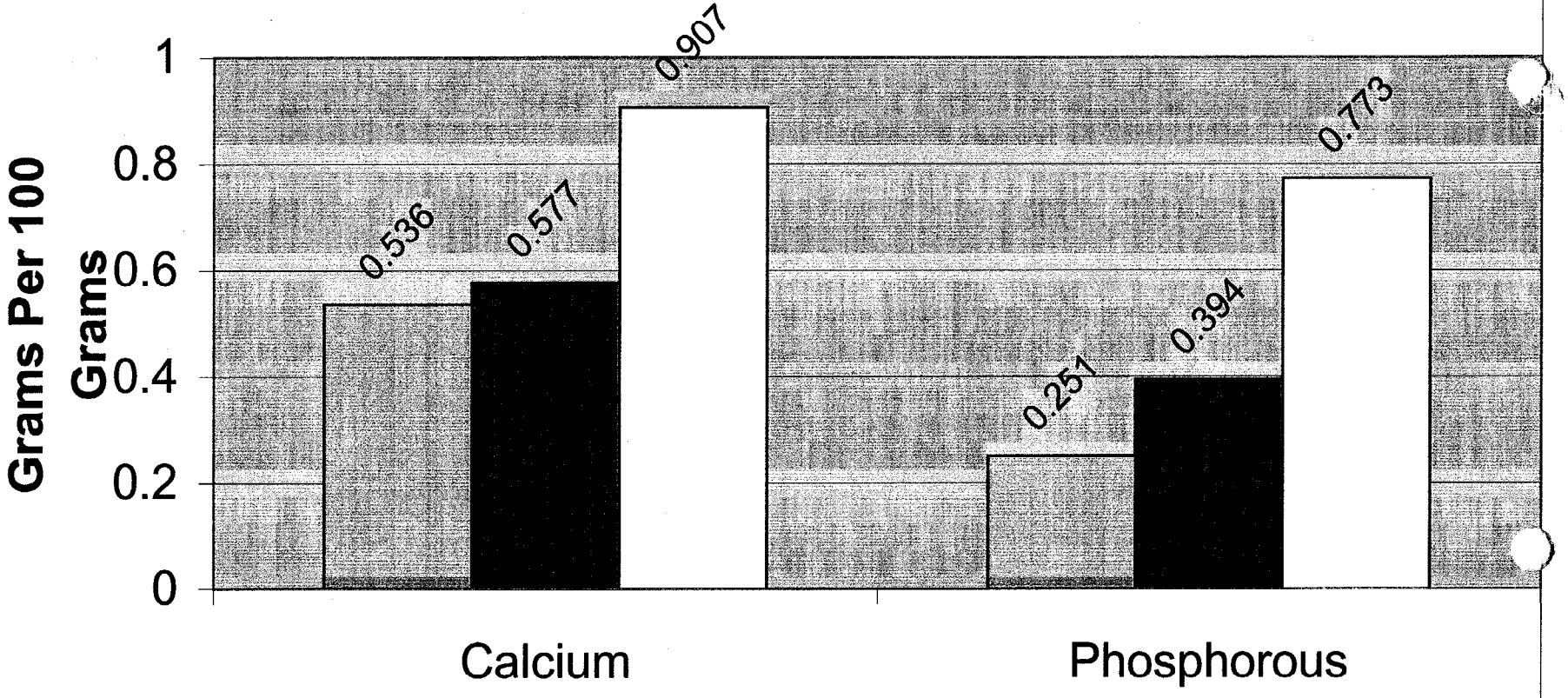
Samples of Cheddar Cheese Made from Filtered Milk Compared to USDA and US Range Values*



* 3 standard deviations from USDA Handbook 8-1 Values

Sutherland and Jameson

Composition of Cheddar Cheese Made from Filtered Milk Compared to US Range Values*

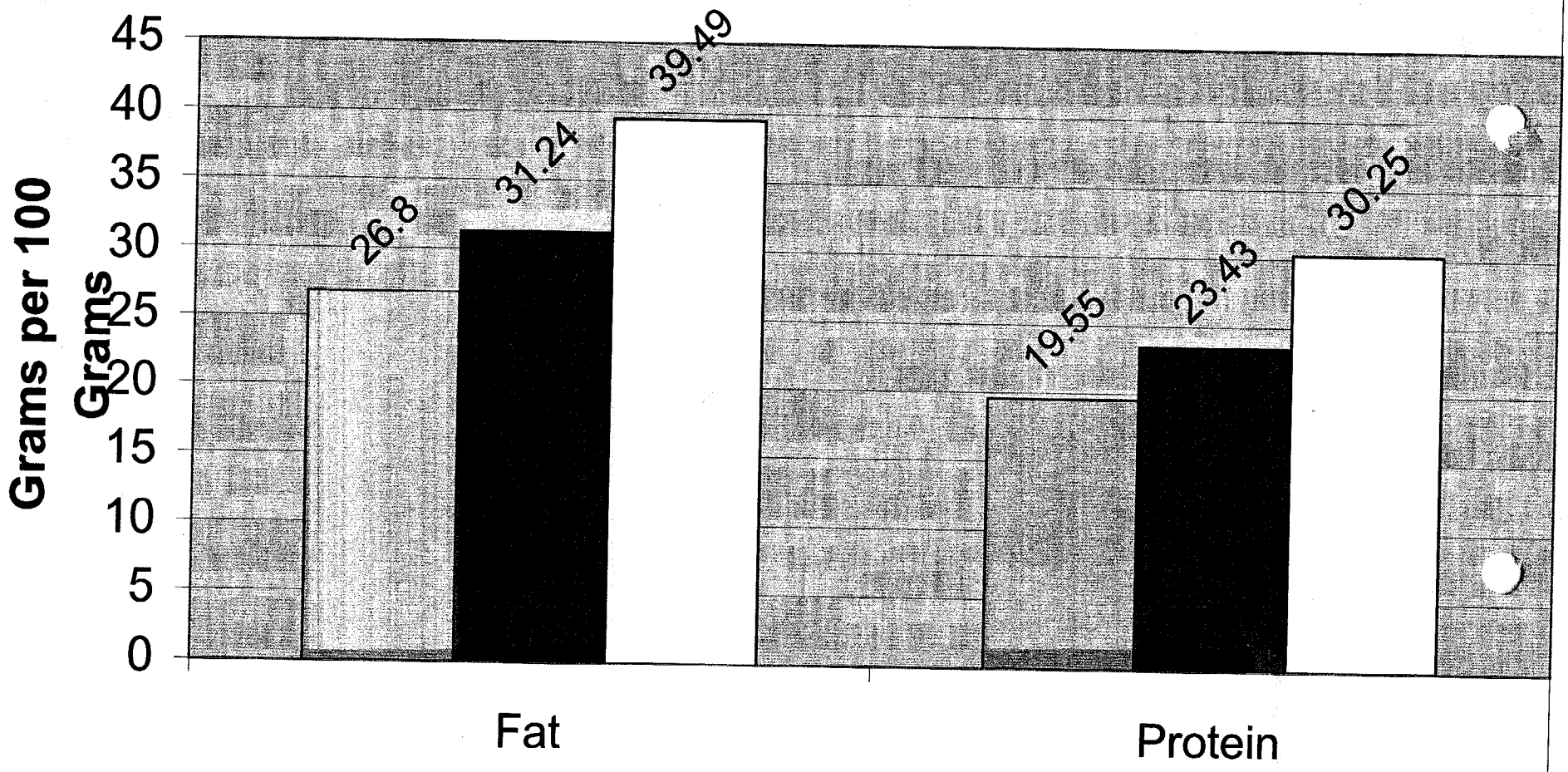


* 3 standard deviations from USDA Handbook 8-1 values

US Range Low ■ Experimental Mean □ US Range High

Sutherland and Jameson

Composition of Cheddar Cheese Made with Filtered Milk Compared to US Range Values*



* 3 standard deviations from USDA Handbook 8-1 values

Sutherland and Jameson--Cheese Composition

Experiment No.	Fat %	Lactose %	Calcium %	Phosphorus %	Protein %	Salt %
1	33.4	0.07	0.772	0.422	22.4	1.73
2	33.4	0.11	0.81	0.415	22.1	1.36
3	32.5	0.84	0.836	0.443	24.1	1.45
4	33	0.47	0.604	0.405	na	1.75
5	31.2	0.1	0.663	0.441	22.9	1.38
6	32.5	0.48	0.585	0.446	22.2	1.68
7	30	1.37	0.633	0.466	22.4	1.74
8	31.5	0.47	0.534	0.369	na	1.54
9	31.7	0.03	0.433	0.328	23.2	1.75
10	30.3	0.16	0.409	0.337	25.2	2.24
11	32.7	0.28	0.447	0.344	23.9	1.85
12	29.7	0.54	0.498	0.38	25.4	1.75
13	31	1.66	0.519	0.397	23.2	1.75
14	24.5	2.15	0.334	0.32	24.1	1.94
Mean	**31.24**	**0.62**	**0.577**	**0.394**	**23.43**	**1.71**

Data from:

Sutherland, B.J., G. W. Jameson. 1981. Composition of hard cheese manufactured by ultrafiltration. The Australian Journal of Dairy Technology. 36(4):136-143.